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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/787,657

03/20/2001

Margaret Ann Johns

5947-01-DRK

4802

7590

01/11/2005

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EXAMINER

GUCKER, STEPHEN

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,657

Applicant(s)

JOHNS ET AL.

Examiner

Stephen Gucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3 and 5-36 is/are pending in the application.
4a) Of the above claim(s) 8-14, 17-20 and 22-34 is/are withdrawn from consideration.
5) ☒ Claim(s) 2,3,5-7,21,35 and 36 is/are allowed.
6) ☒ Claim(s) 15-16 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
3. As correctly noted by Applicant, claim 21 was determined to be in condition for allowance as of the last Office Action, but was inadvertently left out of the previous Office Action.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Line 4 of claim 15 recites a dependency upon claims 1, 2, or 3. Claim 1 has been canceled. Appropriate correction is required.

5. Claim 15 is rejected under 35 U.S.C. 102(a) as being anticipated by Myers for reasons of record and the following. Myers discloses Primer A and Primer B and the amplification conditions used to generate GenBank Accession number G36524 (December 31, 1997), which is described as a human Homo sapiens sequence tagged site (STS) cDNA. The DNA amplification methods used by Myers (initial incubation, denaturation, annealing, polymerization, PCR cycles, etc.) fall within the scope of the instant claim because the amplification primers used comprise at least 8 consecutive

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nucleotides of SEQ ID NO:3 (Primer B by itself comprises nucleotides 3537-3546 of SEQ ID NO:3 and nucleotides 3712-3720 of SEQ ID NO:3). The amplification product obtained comprises 224 nucleotides of SEQ ID NO:3 (nucleotides 3537-3760 of SEQ ID NO:3).

Applicant's arguments filed 7/29/04 have been fully considered but they are not persuasive. Applicant argues that Myers is deficient for not disclosing a pair of amplification primers each comprising at least 8 consecutive nucleotides of a polynucleotide of SEQ ID NO:3. This is misleading because in actual practice, the use of a "pair of primers" is not what is solely being encompassed by the instant method because the method is not literally using a single molecule of one primer and a single molecule of another, different primer (thereby qualifying as a single "pair of primers"). Instead, the method employs multiple copies of the first primer combined with multiple copies of a second primer, i.e. a million copies of the first primer combined with a million copies of the second primer qualify as a "pair of primers." In addition, claim 15 does not require that the two separate primers from a pair of primers be different, that is, instant claim 15 encompasses a "pair of primers" wherein the primers are identical (see page 8, lines 15-17 of the instant specification for possible support for further limiting the scope of the claim to potentially obviate the grounds of this rejection). As noted in the last rejection of record, Primer B of Myers comprises nucleotides 3537-3546 of SEQ ID NO:3 and nucleotides 3712-3720 of SEQ ID NO:3. Different copies or separate molecules of Primer B could therefore hybridize to these two separate regions of SEQ

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ID NO:3 and the portion of DNA of SEQ ID NO:3 between these two separate regions of SEQ ID NO:3 would be amplified, meeting all the limitations of the claim.

6. Claim 16 is rejected under 35 U.S.C. 103(a) as being obvious over Soares et al. ("Soares") for reasons of record and the following. Soares discloses a 328 base pair nucleotide sequence which is an express sequence tag (EST, GenBank Accession Number AA815447) with one mismatch that shares 99.7% identity with nucleotides 1579-1907 of instant SEQ ID NO:3 and was put in the public domain on February 13, 1998. Soares et al. does not explicitly disclose a kit. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a kit containing the nucleotide sequence of Soares for the ease and convenience of having a probe or primer for a voltage-gated calcium channel $\alpha 2\delta$ subunit as disclosed by Soares because of the need to use the probe or primer to identify tissues containing this voltage-gated calcium channel $\alpha 2\delta$ subunit for pharmacological screening assays to search for new anti-convulsant drugs that could block this channel.

Applicant's arguments filed 7/29/04 have been fully considered but they are not persuasive. Applicant argues that the a "DNA sequence of claim 2 or 3" has been found nonobvious, so claim 16 must be nonobvious as well. This is not accurate as the DNA sequence of claim 2 or 3 must encode a polypeptide that is a voltage activated calcium channel $\alpha 2\delta$ -C subunit (instant claim 2) or consist essentially of the DNA sequence shown in SEQ ID NO:3, which encodes a voltage activated calcium channel $\alpha 2\delta$ -C subunit (instant claim 3). Claim 16 does not require that the primers or probes of the kit encode a voltage activated calcium channel $\alpha 2\delta$ -C subunit, so the kit may be found

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obvious while a DNA sequence that hybridizes to SEQ ID NO:3 and encodes a polypeptide that is a voltage activated calcium channel $\alpha 2\delta$ -C subunit and SEQ ID NO:3 itself is not obvious. If Applicant wishes to limit claim 16 to probes and primers that encode a voltage activated calcium channel $\alpha 2\delta$ -C subunit, then this rejection will be withdrawn.

7. Claims 2-3, 5-7, 21, 35 and 36 remain in condition for allowance.
8. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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10. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961. The fax phone number for this Group is currently (571) 273-8300.

SG

Stephen Gucker

January 5, 2005

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600